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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,701	12/17/2001	Dennis Keith	13764-003001	6796

26161 7590 11/16/2004

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,701	KEITH ET AL.	
	Examiner	Art Unit	
	Andrew D Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on October 6, 2004 has been entered.

Claims 1-57 are pending. Claims 1-57 are rejected.

Information Disclosure Statement

References AK-AM do not correspond to a valid U.S. Patent and have not been considered.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Inventorship

Claims 1-6, 13, 22, 24, 26-30, 40, and 53 are directed to essentially the same invention as that of claims 16, 17, 19-24, 34, and 35 of commonly assigned Application No. 10/024,405. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Claims 22, 29, and 45 are directed to essentially the same invention as that of claims 44, 53, and 54 of commonly assigned Application No. 10/023,517. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 13, 22, 24, 26-30, 40, and 53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 17, 19-24, 34, and 35 of copending Application No. 10/024,405 (´405). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to substantially similar methods of preparing crystalline daptomycin lipopeptide, via crystallization from a crystallization solution. Though not relying upon, but in looking to the specifications for support for the methods, it is noted by the Examiner that instant Examples 2-8, 11, and 12 (pages 20-24) are substantially identical to Examples 1-9 of ´405 (pages 14-17).

For example, instant claim 1 is drawn to a method for preparing daptomycin, comprising the steps of:

1) providing an amorphous form of daptomycin; and

2) crystallizing from a crystallization solution comprising:

a) a salt comprising a mono- or di-valent cation,

b) a buffer,

c) an organic precipitant, and

d) a low molecular weight alcohol.

Claim 24 of ´405 is drawn to a method of preparing a crystalline form of daptomycin and daptomycin analogs comprising the step(s) of:

1) combining the lipopeptide with a crystallization solution comprising:

a) at least one cation,

b) at least one polyhyderic or low molecular weight alcohol,

c) one or more of organic precipitants, pH buffers, low molecular weight alcohols, and detergents.

d) an organic precipitant PEG.

The claims differ in that the instant claims provide the amorphous form, while ´405 is silent to the pre-crystallization form. It is the Examiner's position that providing amorphous daptomycin will solubilize in solution and be indistinguishable from any other form of daptomycin in solution, and that in practicing each of the claimed methods one would intrinsically form crystalline daptomycin. The instant claims further differ in that ´405 lists more components of the crystallization solution. Because the recited

components of the buffer solution are conventional and so few in number, one of ordinary skill in the art could readily envisage all of the possible permutations of such a solution.

The claims substantially overlap in that they both are methods *comprising* the step(s) which result in crystalline daptomycin and both solutions *comprise* the listed components and do not exclude any of those listed. Further, the instantly claimed invention encompasses and/or is encompassed by the claimed invention of ´405. Thus, by practicing one method you would be intrinsically practicing the other.

Claims 1-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44-56 of copending Application No. 10/023,517 (´517). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to substantially similar methods of preparing crystalline or crystal-like daptomycin lipopeptide from amorphous lipopeptide, via crystallization or precipitation from a crystallization solution. Though not relying upon, but in looking to the specifications for support for the methods, it is noted by the Examiner that instant Examples 1-13 (pages 19-25) are substantially identical to Examples 1-13 of ´517 (pages 36-42).

For example, instant claim 45 is drawn to a method for preparing crystalline or crystal-like daptomycin with at least 95 % purity from daptomycin which is no greater than 90 % pure (as a starting material), comprising the steps of:

1) providing an solution comprising:

a) daptomycin

b) a salt comprising a mono- or di-valent cation,

c) a pH buffering agent, and

d) a low molecular weight or polyhydric alcohol; and

2) allowing crystallization or precipitation from solution.

Claim 54 of ´517 is drawn to a method for storing daptomycin, or generically to related lipopeptides, which is more than 95 % pure from daptomycin which is approximately 90 % pure (starting material) comprising the steps of:

1) providing an solution comprising dissolved lipopeptide,

2) crystallizing or precipitating from solution,

3) collecting and drying the lipopeptide, and

4) storing the lipopeptide;

wherein the amorphous form is less stable than the crystalline form.

It is intrinsic to the method of 'storing' that one would be practicing the method of 'preparing', as steps 1 and 2 of ´517 overlap in scope with steps 1 and 2 of the instant claimed 45. Further the purity of the starting material and final product are of overlapping scope. In looking to the specification to define the 'solution' for crystallization, ´517 teaches that it comprises salts, pH buffering agents and low molecular weight or polyhydric alcohols (page 12, line 24+).

The instant claims recite 'amorphous' daptomycin and ´517 recites that the amorphous form is less stable than the crystalline product. It is the Examiner's position that in practicing each of the claimed methods one would intrinsically form crystalline daptomycin from amorphous daptomycin.

The claims substantially overlap in that they both are methods *comprising* substantially similar step(s) and solutions which result in crystalline daptomycin. Further, the instantly claimed invention encompasses and/or is encompassed by the claimed invention of '517. Thus, by practicing one method you would be intrinsically practicing the other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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